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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,514	04/30/2002	Patrick Duwat	0384-0049-0 PCT	3030
22850	7590	05/12/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			MARX, IRENE	
			ART UNIT	PAPER NUMBER

1651

DATE MAILED: 05/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/508,514

Applicant(s)

DUWAT ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 24-26, 34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-13 and 27-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The application should be reviewed for errors. Error occurs, for example, in the use of multiple “and” clauses in claim 17, rendering the antecedent basis at least for “complexes” confusing.

The amendment filed 4/14/04 is acknowledged. Claims 1-23, 27-33 are being considered on the merits.

The amendment presented is improper in that the status of claims is not correctly indicated. For example “withdrawn” claims are not properly identified as such.

Claims 24-26, 34 and 35 are withdrawn from consideration as directed to a non-elected invention.

The continued traversal of the lack of unity requirement is noted. However, applicants have not demonstrated a nexus between “superior preservation and acidification properties” of various and sundry lactic acid bacteria and the claimed process with appropriate objective evidence. The only strains that may possess the touted property are the specific *Lactococcus lactis subsp. cremoris* strains of claim 32. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence.

This application contains claims 24-26, 34 and 35 drawn to an invention nonelected with traverse in Paper filed 8/25/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The amendment filed 4/14/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In the specification at page 5, the recitation of “at least 5 micromoles per liter of culture medium” rather than “millimoles” are originally recited.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the recitation of "at least 5 micromoles per liter of culture medium" as amended in claim 19 and in the specification at page 5.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The specification as amended now reads "aerated so as to maintain, during the entire duration of the culture, an oxygen content which is equal to at least 5 **micromoles** per litre of culture medium, preferably from 8 to 45 **millimoles** per litre of culture medium." This recitation is inconsistent and contradictory.

The arguments by applicant to the effect that the amount of dissolved oxygen has an upper limit in the micromoles is contrary to the written disclosure and claimed invention directed to "**at least**" 5 **micromoles** per litre, wherein the upper limit is infinite. Moreover, the discussion regarding extraordinary measures required to grow bacteria at the level of 5 millimoles per liter has not been substantiated with appropriate evidence, and, in any event, would be contradictory and inconsistent with the claimed designated invention.

It is also of interest to note that this material was filed without amendment in PCT/IB99/01430.

Rejections under 35 U.S.C § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel strains of *Lactococcus*. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed only for strain *Lactococcus lactis subsp. cremoris* CHCC373 as noted on page 16 of the specification. However, it is not clear that the other strains as claimed are deposited and if all of the deposits meet all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

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7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claims 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keitel, Heuser, Treschow *et al.*, or DE 2440516 taken with Kaneko *et al.* and El-Megeed *et al.* ~~as~~ for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to a process of producing a starter culture of lactic acid bacteria by culturing aerobically in the presence of at least one porphyrin compound.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants' definition of "aeration" is provided at page 5, lines 6-8 and states "aeration can be effected by any means known by one skilled in the Art, for example by shaking or stirring the culture medium or by passing a gaseous mixture containing oxygen such as air into the culture medium". The definition now provided requiring that "fresh air or oxygen is continuously provided and distributed in the whole culture" is not consonant with applicants' definition in the specification and with the knowledge in the art. In any event, it is well settled that claims are given their broadest reasonable interpretation. Therefore, aeration is interpreted as meaning that the culture medium is exposed to air at least to some extent.

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Regarding Keitel, counsel acknowledges that a stirring mechanism is present but baldly states that because the pH reaches a value of 3.7 to 3.8, the stirring must be in a closed vessel and/or under N₂ atmosphere. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence.

With respect to Heuser, Counsel baldly states that because the lactic acid content reaches 0.5 to 1.5% aeration is ruled out. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence.

As to Treschow, applicant addresses the inoculation of blood with lactic acid bacteria, and indicates that the method is not under aeration because it is a "fermentive process". If the process intended is "fermentation" process, please note the definition of "fermentation" in "*Biotechnology from A to Z*" which adequately demonstrates that it is proper in this art to encompass growing microbes in liquid under any conditions. That a process is indicated as being "fermentative" is not in itself informative of any process conditions.

Regarding the German patent, DE 2440516, applicant alleges that the strains are cultured under N₂ and CO₂. However, this is true only of the initial selection step in petri dishes. Subsequently, the colonies obtained are inoculated with a loop into tubes which are incubated to ascertain gas production (See, e.g., page 17, last paragraph). It is not apparent that precautions are taken to ensure strictly anaerobic conditions. Therefore, it can reasonably be expected that there is aeration by air at least to some extent.

As correctly noted by applicant, El-Megeed *et al.* is relied upon for its teaching of producing a starter culture of lactic acid bacteria wherein the *Lactobacillus* are refrigerated for storage or freeze dried for this purpose.

Applicant's attempt to distinguish over Kaneko with arguments regarding the greater viability of starter cultures in Tables III and IV at pages 14-15 of the specification are noted. However, the results touted pertain to strain *Lactococcus lactis subsp. cremoris* MG1363 cultured in medium "M17" supplemented with glucose and 10 µg/ml of hemin and aerated. It is noted that the control culture is provided neither with hemin nor aeration. These results are not probative of unexpected results for the claimed invention. All they demonstrate is that strain

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Lactococcus lactis subsp. cremoris MG1363 survives better when stored at 4° C whenever it is grown in medium "M17" supplemented with glucose and provided with 10 µg/ml of hemin and aerated. The results are not informative for the effects of culturing any strain of lactic acid bacteria on any nutrient medium containing any porphyrin in any amount, including traces. Moreover, applicant's extensive arguments regarding the difference between growth and survival are not persuasive of the merits of the claim designated invention.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

No claim is allowed.

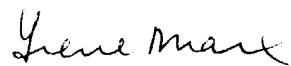
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 703-308-2922. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0926.



Irene Marx

Primary Examiner